

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

QUESTIONS TO THE ADVISORY COMMITTEE

AUGUST 11, 2009

1. (Discussion) Do the preclinical and clinical data demonstrate that DaTSCAN allows visualization of the dopamine transporter distribution within the human brain striatum?
2. (Discussion) Three phase 3 clinical studies assessed DaTSCAN images in comparison to clinical diagnoses (clinically diagnosed dementia or movement disorders).
 - a. Is clinical diagnosis, as formed in these studies, a satisfactory diagnostic standard ("standard of truth") for the detection of abnormal dopamine transporter distribution within the human brain striatum?
 - b. Does the acceptability of this standard depend on whether the clinical population had dementia or movement disorders?
3. (Vote) Do the available data indicate a favorable risk to benefit profile for use of DaTSCAN as a tool to assist clinicians in the evaluation of patients with symptoms or signs suggestive of dopaminergic neurodegeneration?
 - a. If you answered, "no," discuss the types of clinical data that would be necessary to change your opinion.
 - b. If you answered, "yes," discuss whether the favorable profile applies to all patients or only specific subsets (e.g., only dementia or only movement disorders).
4. Discuss any considerations you regard as important for labeling or for subsequent clinical studies you believe should be performed.